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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,799	08/24/2001	Bettina Mockel	32301WD195	9044

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EXAMINER
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KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/935,799	<b>Applicant(s)</b> MOCKEL ET AL.	
	<b>Examiner</b> Kathleen M Kerr	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5,8-30,32,37-41 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) 12-26 and 28-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,8,11,27,32 and 38 is/are allowed.
- 6) ☒ Claim(s) 37,39,40,43,45 and 46 is/are rejected.
- 7) ☒ Claim(s) 9,10,41,44 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on February 23, 2004), Applicants filed a response and amendment received on April 29, 2004. Said amendment amended Claims 9, 10, 32, 38, 39, 41, 44, 46, and 47 and cancelled Claims 31, 33-36, and 42. Thus, Claims 5 and 8-30, 32, 37-41, and 43-47 are pending in the instant Office action. Claims 12-26 and 28-30 remain withdrawn from consideration as non-elected inventions. Claims 5, 8-11, 27, 32, 37-41, and 43-47 will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 42 051.6 filed in Germany on August 26, 2000 as requested in the declaration. Receipt was previously acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Applicants have also filed a certified translation of the German priority document.

### ***Withdrawn - Claim Objections***

3. Previous objection to Claim 32 for a typographical error is withdrawn by virtue of Applicant's amendment.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

4. Previous rejection of Claim 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “vector which carries a polynucleotide” is withdrawn by virtue of Applicant’s amendment as suggested by the Examiner.
5. Previous rejection of Claim 31 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “said polynucleotide is native to *Corynebacterium glutamicum*” is withdrawn by virtue of Applicant’s cancellation of said phrase.
6. Previous rejection of Claims 33-35 and 46 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “carbon starvation protein A activity” is withdrawn by virtue of Applicant’s cancellation and/or amendment to said claims.
7. Previous rejection of Claims 39-40 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “a complete complement of SEQ ID NO:1” is withdrawn by virtue of Applicant’s amendment as suggested by the Examiner.
8. Previous rejection of Claims 38 and 46 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant’s amendment.
9. Previous rejection of Claims 31, 35, and 46 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant’s cancellation and/or amendment of said claims to remove all reference to being native to *Corynebacterium glutamicum*.

Art Unit: 1652

10. Previous rejection of Claims 36 and 46 are rejected under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicant's cancellation and/or amendment to said claims.

11. Previous rejection of Claims 10 and 46 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment limiting the term "overexpression" to include only increasing *cstA* copy number or linking *cstA* to a promoter. Such modes of overexpression are clearly enabled by the state of the art.

12. Previous rejection of Claims 36 and 46 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation and/or amendment to said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

13. Previous rejection of Claims 9, 41, 42, 44, 46, and 47 under 35 U.S.C. § 102(b) as being anticipated by Eikmanns *et al.* as evidenced by GenBank Accession Number BX927149 is withdrawn by virtue of Applicant's amendment, which requires transformation of the bacterium with *cstA*.

14. Previous rejection of Claims 33-35, 38, 42, and 46 under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00804) is withdrawn by virtue of Applicant's cancellation and/or amendment to said claims.

Art Unit: 1652

15. Previous rejection of Claims 33-35, 38, 42, and 46 under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790) is withdrawn by virtue of Applicant's cancellation and/or amendment to said claims.

## **NEW ISSUES**

### ***Claim Objections***

16. Claims 9, 10, 41, 44, and 47 are objected to for containing arduous language. The Examiner suggests that, in each claim, the final "wherein" clause is deleted and "comprising" in the first line of each claim is replaced with ---transformed with--- for more simple language. Moreover, in Claim 9, the first "wherein" clause is unnecessary since the polynucleotide is already specifically defined by SEQ ID NO:1 (which inherently encodes SEQ ID NO:2); deletion of this phrase is also suggested.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 37, 43, and 46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 37, the phrase "encodes a protein consisting of the amino acid sequence of SEQ ID NO:2" (emphasis added) is unclear because the article ---a--- indicates that a genus follows; however, there is only one protein consisting of amino acid

Art Unit: 1652

sequence SEQ ID NO:2. Thus, the article must be ---the--- to indicate a species properly.

Correction is required.

18. Claims 39, 40, and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 39, the phrase “**consisting of at least 30 consecutive nucleotides**” (emphasis added) is unclear as to whether the language is open or closed. At their broadest (see M.P.E.P. § 2111), the claims can be interpreted as ---consisting of at least 30 consecutive nucleotides--- *attached to anything else*, which is the essence of “comprising”. At their most limited, the claims might encompass ---consisting of a DNA fragment of SEQ ID NO:1 wherein said fragment consisting of at least 30 consecutive nucleotides--- which language limits to fragments of SEQ ID NO:1 from 30 nucleotides to 2718 nucleotides (the full-length) and nothing else. In view of the dual interpretation of the claims, clarification is required. If the closed interpretation is intended, the Examiner suggests the latter language.

19. Claims 39, 40, and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 39, it is unclear if the claimed polynucleotide consists of (a) at least 30 consecutive nucleotides of SEQ ID NO:1 or (b) the complete complement of SEQ ID NO:1 ... or if the claimed polynucleotide consists of (i) at least 30 consecutive nucleotides of SEQ ID NO:1 or (ii) *at least 30 consecutive nucleotides of the*

Art Unit: 1652

complete complement of SEQ ID NO:1. If the latter is intended, the Examiner suggests using itemization for clarity. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 43 and 45 are rejected under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to bacteria comprising a polynucleotide consisting of a certain length, in the absence of other polynucleotide (i.e., like a vector). To make such an invention would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by



Art Unit: 1652

weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The nature of the invention is containing, within a bacterium, a piece of DNA with nothing else attached, i.e., no vector, no label, etc. In the art, such "naked" DNA is quickly degraded within a bacteria. The specification has not provided, by way of example or guidance, means for producing the claimed bacteria. The state of the prior art offers no aid in producing such a host cell. Thus, the ability to make the claimed invention is wholly unpredictable. Thus, the instant claims lack enablement.

### ***Summary of Pending Issues***

21. The following is a summary of the issues pending in the instant application:

- a) Claims 9, 10, 41, 44, and 47 stand objected to for containing arduous language.
- b) Claims 37, 43, and 46 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "encodes a protein consisting of the amino acid sequence of SEQ ID NO:2" (emphasis added).
- c) Claims 39, 40, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "**consisting of at least** 30 consecutive nucleotides" (emphasis added).
- d) Claims 39, 40, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the scope of the noted complement in the claim.
- e) Claims 43 and 45 stand rejected under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement.

Art Unit: 1652

***Examiner's Comment***

22. The Examiner would like to reiterate the relevancy of WO 01/00804 (Pompejus *et al.*, see IDS) with an international filing date of June 23, 2000 (published on January 4, 2001 and, thus, not available as prior art) claiming priority to three U.S. provisional applications with priority dates also before the earliest effective filing date of the pending claims. The teachings of Pompejus *et al.* are described in the Office action mailed September 9, 2003 - while SEQ ID NO:1 is not taught, a DNA encoding SEQ ID NO:2 is taught.

***Conclusion***

23. Claims 5, 8, 11, 27, 32, and 38 are allowed. Claims 9, 10, 41, 44, and 47 are objected to. Claims 37, 39, 40, 43, 45, and 46 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** due to the new grounds of rejection cited herein, in particular Claims 37, 43, and 45 are *not* considered allowable herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kathleen M Kerr'.

Kathleen M Kerr  
Examiner  
Art Unit 1652

June 11, 2004